**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION of

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| Inventor | : | DALEY |
| Appln. No. | : | 09/670,781 |
| Conf. No.: | : | 6751 |
| Filed: | : | September 27, 2000 |
| Title: | : | SYSTEM, METHOD AND PACKAGE FOR PROVIDING A LIQUID SOLUTION |
| Group Art Unit | : | 1761 |
| Examiner | : | WEINSTEIN, S. |
| Docket No. | : | 00-39 RCE 1, PH 011149US1 |

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**MS Appeal Brief Patents**
**Commissioner for Patents**
**P.O. Box 1450**
**Alexandria, VA 22313-1450**

**ATTENTION: Board of Patent Appeals and Interferences**

## AMENDED APPEAL BRIEF (37 C.F.R. § 41.37)

Appellant hereby submits this Amended Appeal Brief in response to the January 21, 2009 Notification of Non-Compliant Appeal Brief. This Amended Brief is filed on March 21, 2009, which is within one month of the expiration of the one-month deadline set forth in the January 21, 2009 Notification. The Commissioner for Patents is hereby authorized to charge the corresponding $130 one month extension fee under 37 CFR 1.117(a)(1) to Deposit Account Number 14-1270.

This submission sets forth the authorities and arguments upon which Appellant relies in support of the appeal from the final rejection of claims 1-4, 6, 7, 10, 12, 13, 15-17, and 18-39 in the Office Action dated March 13, 2006 of the above-identified patent application.

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## I. REAL PARTY IN INTEREST (37 C.F.R. § 41.37(c)(1)(i))

The real party in interest in the above-identified patent application is RIC Investments, LLC as the assignee which was recorded on October 18, 2005 at reel/frame: 016653/0709. RIC Investments, LLC is a subsidiary of Respironics, Inc.

## II. RELATED APPEALS AND INTERFERENCES (37 C.F.R. § 41.37(c)(1)(ii))

There are no other related appeals, interferences, or judicial proceedings known to Appellant, Appellant's legal representatives, or Assignee which may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

## III. STATUS OF CLAIMS (37 C.F.R. § 41.37(c)(1)(iii))

### A. Status of All Claims in the Application

1. Claims pending: 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39.
2. Claims rejected: 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39 (via the March 13, 2006 Final Office Action).
3. Claims allowed: none.
4. Claims canceled: 5, 8, 9, 11, 14, and 18.
5. Claims withdrawn from consideration (e.g., by election/restriction) but not canceled: none.
6. Claims objected to: none.

### B. Claims on Appeal

Appellant appeals all pending claims (claims 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39).

## IV. STATUS OF AMENDMENTS (37 C.F.R. § 41.37(c)(1)(iv))

Appellant has not filed an After Final Amendment. Thus, the pending claims are the claims presented in Appellant's May 4, 2005 Amendment

## V. SUMMARY OF THE CLAIMED SUBJECT MATTER (37 C.F.R. § 41.37(c)(1)(v))

Appellant provides the following concise, non-limiting explanation of example subject matter of appealed the claims, with parenthetical citations to the original application.

An embodiment of the claimed subject matter, as recited in claim 1, is shown in Fig. 1 and described at p. 4, ll. 12-30. This embodiment is a packaged solution having a cup-shaped

container (10) that is shaped to have a width that is greater than the depth and has a cavity (12) which opens to a mouth (16). Disposed inside the container is a volume of a solution (18) that comprises sucrose and water. Specifically, the solution (18) comprises about 10% to about 50% sucrose while the remainder of the solution (18) is water. The container is sealed with a cover (20) disposed over the mouth (16). Both the solution (18) and an interior of the container (10) are in an aseptic state.

Another embodiment of the invention, as recited in claims 12 and 17, is shown in Fig. 3 and described at p. 6, ll. 5-13. This embodiment is a method for providing a solution (18) for use in conjunction with a planned medical procedure on a neonatal infant. The method includes preparing the solution (18) comprising sucrose and water, packaging the solution (18) in single-use containers (10), assembling a plurality of the single-use containers (10) in a shipping container (30), and shipping the shipping container (30), shown in Fig. 2, to an intended site of usage of the solution (18). Next, the method includes opening an individual, single-use container (10) of the solution (18) prior to the planned medical procedure, administering a selected volume dose of the solution (18) orally to the neonatal infant, and discarding any residual solution (18) within the opened, individual, single-use container (18) after the planned medical procedure.

Yet another embodiment of the claimed subject matter, as recited in claims 23 and 29, is shown in Fig. 1 and described at p. 4, ll. 12-30. This embodiment includes a packaged solution for use in conjunction with a medical procedure performed on an infant. The packaged solution includes a cup-shaped container (10) having a width that is greater than the depth defining a cavity (12). The container also has an inner surface and opens to a mouth (16) so that an object such as a pacifier may be inserted into the container. The cup-shaped container (10) also includes a flange (14) extending outwardly about the mouth (16). In claim 23, the container (10) is made from a polymeric material. A volume of a solution (18) comprising sucrose and water is disposed within the cavity (12). In claim 23, the solution is approximately 24% sucrose and 76% water. In claim 29, the solution is between 10% and 50% sucrose. A cover (20) is disposed over the mouth (16) to seal the solution (18) within the cavity (12). The cover seals at least a portion of the top surface of the flange (14) and has a tab (14b) extending beyond the periphery of the flange (14) such that the user can easily grasp and remove the cover (20).

Another embodiment of the present invention, as recited in claim 37, is shown in Fig. 3 and described at p. 6, ll. 5-13. This embodiment is a method of producing a packaged solution

assembly for use in conjunction with a medical procedure on an infant. This method includes the steps of providing a cup-shaped container (10) having a width sized to receive at least a portion of an object therein. The cup-shaped container (10) defines a cavity (12) that opens to a mouth (16) and a flange (14) that extends about the mouth (16) of the cavity (12). The next step of this method includes mixing between 10% to 50% sucrose with water to create a sucrose solution (18), transferring the sucrose solution (18) into the cavity (12) of the container (10), and then sealing the container (10) with a cover (20) that is placed over the mouth (16) and sealed with the flange (14) of the container (10).

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL (37 C.F.R. § 41.37(c)(1)(vi))

Appellants appeal each of the following rejections:

A. the rejection of claims 1-4, 6, 7, 10, 21, and 23-36 under 35 U.S.C. § 103(a) as obvious over Lazure (U.S. Patent No. 4,054,207) in view of the Applicant's admission of the prior art as evidenced by the Blass et al. article (AAPA), the Stevens et al. article dated 1997 ("the Stevens 1997 article"), the Stevens et al. article dated 1999 ("the Stevens 1999 article"), the Franck article, further in view of Beckers (U.S. Patent No. 3,654,746), and Hendriks (U.S. Patent No. 4,597,242), Bublitz (U.S. Patent No. 4,211,338), further in view of the Seattle Post-Intelligencer article, Wisconsin State J. article, further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article, further in view of Koch (U.S. Patent No. 2,138,241), Corbic (U.S. Patent No. 4,165,594), Lane (U.S. Patent No. 4,875,620), Sharkey (U.S. Patent No. 5,429,262), Stockdale (U.S. Patent No. 3,390,766), Meisner (U.S. Patent No. 3,478,489), and Christine (U.S. Patent No. 3,414,414); and

B. the rejection of claims 12, 13, 15-17, 19, 20, 22, and 37-39 under 35 U.S.C. § 103 as obvious over AAPA, the Stevens 1997 article, the Stevens 1999 article, the Franck article, the Seattle Post-Intelligencer article, the Wisconsin State J. article, in view of Lazure further in view of Beckers and Hendriks, Bublitz, further in view of Koch, Corbic, Lane, Sharkey, Stockdale, Meisner, and Christine, and further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article.

## VII. ARGUMENT (37 C.F.R. § 41.37(c)(1)(vii))

For at least a decade prior to the filing of the present application, the medical industry knew that an orally administered sucrose solution can alleviate pain in newborns subjected to painful medical procedures. *See* 3/13/06 Office Action, p. 3 ("it was notoriously conventional to provide sucrose solutions useful as an analgesic for newborns"); Blass article, p. 1 ("received for publication August 2, 1989" and published in February 1991). Despite this knowledge, physicians did not give their newborn patients such a sucrose solution because of problems and complications associated with the conventional on-site preparation of a sucrose solution. *See* Evidence Appendix Exhibit C, Physicians' Declarations. Appellant's invention of safe and convenient containers of sucrose solution caused the widespread adoption of such sucrose solutions, as demonstrated by Appellant's and competitor's substantial and successful commercial sales of products embodying the invention. *See* Evidence Appendix, Exhibits B and C.

In the decade prior to Appellant's present invention, if it was obvious to create Appellant's present invention so as to alleviate newborn patients' pain, medical professionals surely would have done so. The fact that they did not clearly proves that the presently claimed invention is not obvious.

### A. The rejection of claims 1-4, 6, 7, 10, 21, and 23-36 under 35 U.S.C. § 103(a) as obvious over Lazure in view of the AAPA, the Stevens 1997 article, the Stevens 1999 article, the Franck article, further in view of Beckers, and Hendriks, Bublitz, further in view of the Seattle Post-Intelligencer article, Wisconsin State J. article, further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article, further in view of Koch, Corbic, Lane, Sharkey, Stockdale, Meisner, and Christine

Appellant appeals the rejection of claims 1-4, 6, 7, 10, 21, and 23-36 under 35 U.S.C. § 103(a) as obvious over Lazure in view of the AAPA, the Stevens 1997 article, the Stevens 1999 article, the Frank article, further in view of Beckers, and Hendriks, Bublitz, further in view of the Seattle Post-Intelligencer article, Wisconsin State J. article, further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article, further in view of Koch, Corbic, Lane, Sharkey, Stockdale, Meisner, and Christine.

Independent claims 1 and 23 each recite, among other things, "a cup-shaped container [] defining a cavity[];a volume of a solution comprising sucrose and water within the cavity[]; and

a cover [] sealing the solution within the cavity." Independent claim 29 similarly recites, among other things, "a cup-shaped container [];a volume of a solution comprising sucrose and water [] within the cavity[]; and a cover [] sealing the solution within the cavity."

In general, the pending obviousness rejection is based on the Office Action's assertion that because (1) "the application of a single serve or single use cups for all type of products, edible, medicinal and inedible, in all sizes and shapes of cups, is notoriously conventional in the art of packaging" (see, e.g., Lazure, Hendriks, Beckers), and (2) "sugar solutions have been formulated to use as a pain relief/calming medium for infants" (see, e.g., Blass, Stevens 1999, Stevens 1997, Frank), it would have been obvious to use such single cups to store medicinal sugar solutions, and that such a modification would result in the combination of recitations in the claims. 7/13/05 Office Action, pp. 2-3; 3/13/02 Office Action, p. 3.

In hindsight, it appears quite simple and elegant to use single use containers to store sugar solutions for medicinal use with newborns. However, Appellant submits that the Office Action fatally confuses the simplicity/elegance of the invention with its obviousness. As explained below, (1) the Office Action has not established a *prima facie* case of obviousness, and (2) even if there were a *prima facie* case of obviousness, the Office Action's improper disregard for Appellant's compelling objective evidence of nonobviousness requires reversal on both procedural and substantive grounds.

### 1. The Office Action has not established a *prima facie* case of obviousness

The Office Action has not established a *prima facie* case of obviousness for the following reasons.

#### a. Lazure teaches away from the proposed combination

The primary asserted reference, Lazure, specifically teaches the use of precisely measured "unit doses of medicine" in a container. *See* Lazure, col. 1, lines 5-6. The purpose of such "unit dose" containers of medicine is to ensure that a patient is administered a correctly measured dose of medicine, thereby avoiding overdosing or underdosing.

The asserted sucrose solution references teach that only a very small dose of sucrose solution (e.g., from 0.05 to 2 ml) is ever administered to a newborn patient. *See, e.g.,* Franck, p. 1 ("Two milliliters of 24% sucrose solution…;" "smaller doses of sucrose (as little as 0.05

ml)"); *see also id*. at p. 2 ("Only a very small drop (less than .05 ml) of the sucrose solution administered by syringe, dropper, or pacifier is needed.").

Lazure expressly teaches away from the Office Action's proposed placement of such sucrose solutions into Lazure's unit dose containers for two reasons.

First, because an appropriate unit dose sucrose solution is so small, if it were placed in Lazure's container, the amount of sucrose solution in the container would be so small that it would be difficult or impossible to administer the entire unit dose to a patient. For example, it would be difficult or impossible to transfer the entire unit dose from in the container to a pacifier for subsequent administration to a patient, particularly in view of how small a unit dose of such a sucrose solution is. Thus, the proposed combination would prevent or seriously impair a physician's ability to administer a full unit dose of sucrose solution to a patient. Such an underdosing result entirely defeats the purpose of "unit dose" teachings such as Lazure. *See* MPEP 2143.01(V) ("If proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."). Moreover, the resulting additional hassle associated with attempting to administer the entire contents of the container are antithetical to the convenience goal of Lazure's "unit dose" container.

Second, to the extent that the pending rejection is based on the assertion that it would have been obvious to fill Lazure's container with more than a unit dose (Appellant disputes the obviousness of this), the resulting combination would no longer contain a unit dose of medicine. Such a result is again antithetical to Lazure's "unit dose" teaching because it defeats the exact unit dose goal of Lazure, and could result in the overdosing that "unit dose" containers seek to prevent. *See* MPEP 2143.01(V) ("If proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."). Put another way, the proposed combination is nonobvious because it would change the Lazure's principle of operation, i.e., the use of a "unit dose" container to ensure the convenient administration of a correct dose of medication. *See* MPEP 2143.01(VI) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.").

For at least these reasons. Appellant submits that Lazure teaches away from the proposed combination, which demonstrates that the proposed combination was not obvious.

**b. The pending rejection impermissibly relies on the combination of nonanalogous art**

The C.C.P.A. stated that when resolving the question of obviousness, we presume full knowledge by the inventor of all the prior art in the field of his endeavor. *In re Wood*, 599 F.2d 1032, 202 U.S.P.Q.2d 1767, 1773 (C.C.P.A. 1979). With regard to prior art outside the field of endeavor, we only presume knowledge from those arts reasonably pertinent to the particular problem with which the inventor was involved. *Id.* A reference in a field different from that of the applicant's endeavor is non-analogous unless "it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole." MPEP 2141.01(a).

In the last Office Action, the Examiner stated that "[i]f 'the problem' is inconvenience, and the potential for waste and contamination, these issues are those that are universally recognized as being addressed by single-use/serve containers." *See, e.g.,* 3/13/06 Office Action, p. 3. From this statement, it appears that the Examiner determined that the relevant art, or field of endeavor, was the container or packaging art. Once so concluded, it does, in theory, seem plausible that one of ordinary skill in the container art would recognize that various foods and/or medications can be stored in single-use/serving containers. However, the field of endeavor for the inventor of the present invention was children's medical devices and not containers.

One of ordinary skill in the children's medical device art would not be likely to reference the container art to find an answer to the problem at hand. This begs the question: what was the problem that the inventor sought to solve? The problem was that doctors were not using sucrose even though sucrose was known to alleviate the suffering and distress of neonates enduring painful medical procedures in neonatal intensive care units as fully described in the Blass article. For those doctors who chose to implement this procedure, the state of the art was to hand-mix sucrose in an on-site kitchen or pharmacy. However, many physicians would simply forgo using sucrose altogether. *See* Evidence Exhibit C, Declaration of Don T. Granger, M.D., ¶ 6; Evidence Exhibit C,

Declaration of Neal Guttenberg, M.D., ¶ 6; Evidence Exhibit C, Declaration of M. David Yohannan, M.D., ¶ 6. It is not obvious that the solution to the problem of physicians not utilizing this procedure would be found by referencing the container art. If anything, the Examiner's conclusion appears to be based upon improper hindsight. Of course, once the problem has been identified and a solution presented, all inventions appear obvious in hindsight. The relevant art, or field of endeavor, for the present invention was children's medical devices. It would not be obvious for one of ordinary skill in the children's medical device art to reference the container art to find a solution to the problem solved by the present invention. Accordingly, the Examiner's rejection is improper for imputing the inventor with knowledge outside the inventor's field of endeavor or reasonably pertinent to the problem sought to be solved.

**c. There was no obvious motivation or other reason to modify or combine the references as proposed by the Examiner**

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727, 1731, 82 USPQ.2d 1385, 1396 (2007) (stating that it is necessary to determine whether there was an "apparent reason" to combine the known elements in the claimed manner); *see also In re Vaeck*, 947 F.2d 488, 495, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991) ("the prior art . . . offers no suggestion, explicit or implicit, of the substitution that is the difference between the claimed invention and the prior art.")

In the present Application, the Examiner has taken the position that obviousness has been established by presenting references that show sucrose is useful as an analgesic for newborns and supplements these references with other references that describe the use of single-use/single-serve containers. *See, e.g.,* 3/13/06 Office Action, p. 3. Applicant contends that what is lacking in the Examiner's rejections is any suggestion, motivation, or other obvious rationale to combine these references as proposed by the Examiner.

**d. Passage of time exhibits a trend away from the present invention**

The Federal Circuit has held that it is proper to consider the "trend" in the art when considering obviousness. *See Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 139

F.3d 877, 45 USPQ2d 1977 (Fed. Cir. 1998). Lazure was filed in 1976 and the Blass article was submitted for publication in 1989. Hospitals and pharmacies, even though they were aware of the analgesic effect of sucrose, have hand-mixed analgesic agents and subjected newborn infants to potentially inconsistent and unsanitary solutions, or declined to use sucrose solutions altogether. Evidence Exhibit C, Declaration of Don T. Granger, M.D. ("Granger Decl."), ¶ 6; Evidence Exhibit C, Declaration of Neal Guttenberg, M.D. ("Guttenberg Decl."), ¶ 6; Evidence Exhibit C, Declaration of M. David Yohannan, M.D. ("Yohannan Decl."), ¶ 6. This, if anything, exhibits a trend away from the present invention. It defies logic to conclude that these skilled health care providers would continue utilizing an inefficient and potentially hazardous process if there was an "obvious" way to correct it.

**e. Recognition of the source of the problem exhibits patentability**

As articulated by the C.C.P.A.:

> A patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the "subject matter as a whole" which should always be considered in determining the obviousness of an invention under 35 USC 103.

*In re Nomiya*, 509 F.2d 566, 184 U.S.P.Q. 607, 612 (C.C.P.A 1975).

As outlined in the background of the present Application, the state of the art was to hand-mix these solutions in an on-site kitchen or pharmacy. *See* Applicant's Application at p. 2, ll. 25-27. Unfortunately, many doctors would forgo using sucrose and needlessly subject distressed infants to further suffering. *See* Evidence Exhibit C, Declaration of Don T. Granger, M.D. ("Granger Decl."), ¶ 6; Evidence Exhibit C, Declaration of Neal Guttenberg, M.D. ("Guttenberg Decl."), ¶ 6; Evidence Exhibit C, Declaration of M. David Yohannan, M.D. ("Yohannan Decl."), ¶ 6. The problem sought to be solved by the Inventor was the lack of sucrose use by physicians and nurses with distressed infants in neonatal intensive care units. The source of the problem was one or more of several issues including: the time involved in mixing the solution, the inconsistency of hand-mixed solutions, the potential for contamination, and the difficulty of applying the solution to a pacifier. *Id.* Recognizing the source of the problem, Applicant proposed an elegant solution as recited in the pending claims. The solution, according to one or more embodiments, was to package a sucrose solution manufactured with a consistent concentration in a convenient container. The art did not recognize the source of the problem. As

such, the art could not propose the unique solution disclosed and claimed in the present Application.

**f. The Office Action has not established a *prima facie* case of obviousness**

The primary reference, Lazure, teaches away from the proposed combination. Moreover, the trend in the art and failure of the art to even recognize the problem indicates that there is no suggestion, motivation, or other obvious reason to combine the references as proposed by the Examiner. For at least these reasons, there is not a *prima facie* case of obviousness of independent claims 1, 23, and 29, as well as their respective dependent claims, and this rejection should be reversed.

**2. Compelling objective evidence of nonobviousness proves the invention's patentability, and the Office Action's improper disregard for this evidence necessitates reversal**

Even if there were a *prima facie* case of obviousness, the compelling objective evidence of nonobviousness proves that claims 1-4, 6, 7, 10, 21, and 23-36 were not, in fact, obvious. The Federal Circuit explains:

> Under *Graham* [*v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)], objective evidence of nonobviousness includes commercial success, longfelt but unresolved need, failure of others, and copying. When present, such objective evidence ***must be considered***. It can be the most probative evidence of nonobviousness in the record and enables the district court to avert the trap of hindsight.

*Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 960, 1 USPQ.2d (BNA) 1196, 1199 (Fed. Cir. 1986) (emphasis added). "[E]vidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39, 218 USPQ (BNA) 871, 879 (Fed. Cir. 1983).

Indeed, even after the *KSR* decision on obviousness, the Federal Circuit has still maintained that the Examiner must consider secondary evidence that rebuts any *prima facie* case of obviousness:

> We agree with applicant that the Board improperly failed to consider the rebuttal evidence and we therefore vacate the Board's decision and remand for the Board to consider the declarations. It is well settled that the PTO "bears the initial burden of presenting a prima facie case of unpatentability… . However, when a prima facie case is made, the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability." *In re Glaug*, 283 F.3d 1335,

> 1338 [62 USPQ2d 1151] (Fed. Cir. 2002). Rebuttal evidence is "merely a showing of facts supporting the opposite conclusion." *In re Piasecki*, 745 F.2d 1468, 1472 [223 USPQ 785] (Fed. Cir. 1984). Evidence rebutting a prima face case of obviousness can include: "evidence of unexpected results," *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1369 [82 USPQ2d 1321] (Fed. Cir. 2007), evidence "that the prior art teaches away from the claimed invention in any material respect," *In re Peterson*, 315 F.3d 1325, 1331 [65 USPQ2d 1379] (Fed. Cir. 2003), and evidence of secondary considerations, such as commercial success and long-felt but unresolved needs, *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 [51 USPQ2d 1385] (Fed. Cir. 1999). When a patent applicant puts forth rebuttal evidence, the Board must consider that evidence. *See In re Soni*, 54 F.3d 746, 750 [34 USPQ2d 1684] (Fed. Cir. 1995) (stating that "all evidence of nonobviousness must be considered when assessing patentability"); *In re Sernaker*, 702 F.2d 989, 996 [217 USPQ 1] (Fed. Cir. 1983) ("If, however, a patent applicant presents evidence relating to these secondary considerations, the board must always consider such evidence in connection with the determination of obviousness.").

*In re Sullivan*, 498 F.3d 1345, 1351, 84 USPQ.2d 1034, 1038 (Fed. Cir. 2007) (remanding finding of obviousness by Board of Patent & Appeals under *KSR* for failing to adequately consider secondary evidence of nonobviousness).

Here, Appellant has provided compelling evidence of competitor adulation for the invention, commercial success of the invention, and long-felt but unmet need for the invention.

Moreover, the Office Action improperly ignored this evidence using erroneous standards to discount/disregard it.

**a. An infringer's adulation for the claimed invention proves its nonobviousness**

The law recognizes that praise or adulation of the claimed invention by others is indicative of nonobviousness. "[S]tatements of praise by the [accused infringer] made prior to the initiation of litigation are a strong indication of the non-obviousness of [the] invention." *Libbey-Owens-Ford Co. v. BOC Group Inc.*, 655 F. Supp. 897, 914, 4 USPQ.2d (BNA) 1097, 1109 (D. N.J. 1987); *see also Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ.2d (BNA) 1378, 1384 (Fed. Cir. 1997) (holding that an infringer's "recognition of the importance of [the patented invention] is relevant to a determination of nonobviousness"); *Minnesota Mining & Manufacturing v. Smith & Nephew PLC*, 25 USPQ.2d (BNA) 1587, 1592 (D. Minn. 1992) ("Insofar as [the accused infringer's marketing] information lends insight into a defendant's actual beliefs about the relative uniqueness, superiority and marketability of a

disputed patent, it has been recognized as valuable in evaluating a defendant's public assertions that a patent was obvious and therefore invalid.").

Here, Appellant's direct competitor, Hawaii Medical, LLC, prominently advertises and promotes the presently claimed invention through its advertisement for its TootSweet product (attached as Evidence Exhibit D). As the advertisement clearly shows, independent claims 1, 23, and 29 clearly cover the TootSweet product. Hawaii Medical's TootSweet advertisement shows clear adulation for the presently claimed invention via its prominent promotion of features that distinguish the presently claimed invention form the prior art:

- "Now there's a safe, convenient way to deliver sucrose solution to your babies – TootSweet™ 24% sucrose solution. TootSweet helps calm and soothe babies in distress and during painful procedures, while protecting against bacterial contamination."
- "More economical and consistent than 'homemade' solutions."
- "cup. Single patient use."

TootSweet Advertisement (Evidence Exhibit D). Such adulation for the presently claimed invention clearly demonstrates that even Appellant's competitor recognized the uniqueness, marketability, and value of the presently claimed invention. Such adulation by an unbiased and independent third party is "a strong indication of the non-obviousness of [the] invention." *Libbey-Owens-Ford*, 655 F. Supp. at 914, 4 USPQ.2d at 1109.

**b. The commercial success of the claimed invention proves its nonobviousness, and the Office Action's erroneous disregard for this evidence further necessitates reversal**

Appellant's assignee's SWEET-EASE™ product (shown in SWEET-EASE™ advertisement attached as Evidence Exhibit A) embodies claims 1, 23, and 29 and has obtained great commercial success.

As outlined in the Declaration of Cathy N. Bush (Evidence Exhibit B) ("Bush Decl."), the SWEET-EASE™ product has had great commercial success:

> The SWEET-EASE™ product was introduced in the market in 2001. Since its introduction in 2001, the SWEET-EASE™ product has experienced amazing success…. In 2003, only 2 years after introduction, total sales were approximately 2.4 million cups for approximately $1.7 million in sales. This volume and adoption by the marketplace far exceeds both the typical growth of new products and our original expectations for this product.

Bush Decl., ¶ 3.

Ms. Bush compares the SWEET-EASE™ product with the HEEL HUGGER™ product. *Id.* at ¶ 4. Both products are disposable, single-use products used on infants and sold by the Appellant's assignee. Even though the SWEET-EASE™ product had been in the industry for less than half as long, it achieved approximately six times as many sales in 2003. *Id.*

Ms. Bush demonstrates that the commercial success of the SWEET-EASE™ product is directly attributable to its use of the presently claimed invention:

> I believe that these extraordinary sales results are because the SWEET-EASE™ product provides a convenient, aseptically packaged container filled with a sucrose solution not previously available in the medical industry. Research validating the effectiveness of sucrose to calm and sooth babies has been available since the late 1980's. However, because there was not a convenient, safe method for sucrose delivery, few hospitals were utilizing it even though it was shown to be effective.

*Id.* at ¶ 5. Physicians' subsequent purchase and use of the SWEET-EASE™ product based on its practice of the presently claimed invention demonstrates a clear nexus between the commercial success and the presently claimed invention. *See* Evidence Exhibit C, Declaration of Don T. Granger, M.D., ¶¶ 6-7; Evidence Exhibit C, Declaration of Neal Guttenberg, M.D., ¶¶ 6-7; Evidence Exhibit C, Declaration of M. David Yohannan, M.D., ¶¶ 6-7.

Moreover, the focus of the SWEET-EASE™ advertisement (Evidence Exhibit A) and the competing Tootsweet advertisement (Evidence Exhibit D) on features that distinguish the presently claimed invention from the prior art provide further evidence of the nexus between the commercial success and the present invention. *See Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ.2d (BNA) 1378, 1384 (Fed. Cir. 1997) ("The prominence of the patented technology in [the infringer's] advertising creates an inference that links the [] invention to this [commercial] success"); *see also Bose Corp. v. JBL, Inc.*, 112 F. Supp.2d 138, 156 (D. Mass. 2000) ("[an infringer's] adulation of the [product] is the best evidence of the extent of its commercial success.").

This evidence of the commercial success of products embodying claims 1, 23, and 29 strongly demonstrates the nonobviousness of these claims.

The latest Office Action disregarded this commercial success evidence on the ground that it failed to "present any unexpected evidence." 3/13/06 Office Action, p. 3; *see also* 1/5/05 Office Action, p. 4 (disregarding this commercial success evidence because the commercial success of the claimed invention "is an expected result"). However the relevance and weight of

commercial success evidence has nothing to do with whether the commercial success would be "expected" in the eyes of the Examiner Indeed, commercial success objectively refutes the Office Action's unsupported allegation, else someone in the prior art would have adopted the invention to make money. Indeed, this is the entire basis of commercial success as an objective standard for assessing obviousness. It appears that the Office Action fatally confused the requirements of commercial success evidence with the requirements of unexpected results evidence. Thus, the Office Action disregarded this compelling commercial success evidence on improper grounds.

An earlier Office Action disregarded this commercial success evidence on equally improper grounds. In particular, the January 5, 2005 Office Action disregarded this commercial success evidence because separate recitations of the invention recited in claims 1, 23, and 29 were known to be advantageous. *See* 1/5/05 Office Action, p. 4 (discrediting commercial success evidence because "the convenience of single use containers containing food or medicinals is not an unexpected result" and "the use of a sucrose solution as an analgesic for newborns is well established in the art."). In addition to any such "expectation" being irrelevant to commercial success, Appellant specifically traverses the Office Action's disregard for this commercial success evidence based on the Office Action's assertion that the individual recitations of the claims were known to be advantageous in the prior art. The Examiner is basically saying that because the distinguishing elements of the claimed combination are known to be beneficial, there can be no evidence of commercial success. This reasoning defies the logic of commercial success rebuttal evidence. Under such an analysis, all evidence of commercial success could be ignored based on the assertion that a given feature is known in the art, because presumably every *prima facie* case of obviousness teaches all the elements of the claim, but not in the same combination as claimed. As such, an Examiner could always point to some feature as already being known (assuming a proper *prima facie* case with all the claim elements in the prior art has been made) and take the same conclusory position as the Office Action in this application. However, the point of commercial success evidence is to show the success in the marketplace of the entire claimed invention, and that the success is attributable to the feature(s) that differentiate the claimed invention from the competing products that preceded it. *See In re Huang*, 100 F.3d 135, 140, 40 USPQ.2d (BNA) 1685, 1690 (Fed. Cir. 1996) (holding that commercial success evidence must show that the commercial success was "a direct result of the

unique characteristics of the claimed invention."). That is exactly the evidence presented here, and it is impermissible for the Office Action to disregard this evidence on the basis of individual elements or their benefits being known.

The Office Action's summary dismissal of Appellant's commercial success evidence should be reversed as legally unsound.

**c. The long-felt, unresolved need for the claimed invention proves its nonobviousness, and the Office Action's erroneous disregard for this evidence further necessitates reversal**

There has been a long-felt but unmet need for a way to soothe newborn patients that was safe and convenient enough to actually convince physicians to use it. Indeed, Appellant submits that physicians have eternally been looking for ways to sooth such newborn patients undergoing painful medical procedures.

As described in the attached declarations of three board-certified neonatologist physicians, although sucrose solutions have been known to have soothing properties for at least a decade, physicians have not been able to safely and conveniently use sucrose solutions, and instead have had to resort to attempts to "console the newborn by rocking or patting." Evidence Exhibit C, Declaration of Don T. Granger, M.D. ("Granger Decl."), ¶¶ 5-6; Evidence Exhibit C, Declaration of Neal Guttenberg, M.D. ("Guttenberg Decl."), ¶¶ 5-6; Evidence Exhibit C, Declaration of M. David Yohannan, M.D. ("Yohannan Decl."), ¶¶ 5-6. The state of the art was to hand-mix sucrose solutions in an on-site kitchen or pharmacy; yet, hand-mixing may contaminate the solution, result in wasted time, and the creation of inconsistent solutions. *Id.* Indeed, "manually mixing a sucrose solution could prove dangerous and even life threatening to these sick newborns." Granger Decl., ¶ 6; *see also* Guttenberg Decl., ¶ 6 (same); Yohannan Decl., ¶ 6 (same). These complications and concerns caused physicians to forego the use of sucrose solutions despite the known benefits of such solutions. *See* Granger Decl., ¶ 6 ("For this reason, I am unwilling to personally mix a sucrose solution or to instruct others to do so."); *see also* Guttenberg Decl., ¶ 6 (same); Yohannan Decl., ¶ 6 (same). Thus, "there has long been a definite need in [the medical] industry for some way to calm and sooth these newborns." Granger Decl., ¶ 7; *see also* Guttenberg Decl., ¶ 7 (same); Yohannan Decl., ¶ 7 (same). The invention claimed in clams 1, 23, and 29, as embodied in "the SWEET-EASE™ product meets this need" by providing a safe, convenient way of administering sucrose solutions to newborn

patients, thereby causing physicians to actually administer such beneficial solutions to their newborn patients. Granger Decl., ¶ 7; *see also* Guttenberg Decl., ¶ 7 (same); Yohannan Decl., ¶ 7 (same).

A noted jurist, Judge Easterbrook, described the value of such long-felt need evidence in an oft-quoted and highly accurate fashion:

> The existence of an enduring, unmet need is strong evidence that the invention is novel, not obvious, and not anticipated. If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence--the kind that can't be bought from a hired expert, the kind that does not depend on fallible memories or doubtful inferences--of the state of knowledge.

*In re Mahurkar Patent Litigation*, 831 F. Supp. 1354, 1377-78, 28 U.S.P.Q.2d (BNA) 1801, 1819 (N.D. Ill. 1993), *aff'd,* 71 F.3d 1573 (Fed. Cir. 1995). This principle underlying evidence of a long-felt but unsolved need is simple. If an industry was trying to solve a problem for years, and yet never created the claimed invention, the invention could not have been obvious – or else someone would have invented it earlier to satisfy that need. Here, if an obvious product would have caused physicians to safely and conveniently sooth their newborn patients, such a product would have surely been adopted in a widespread manner long ago. The fact that such a product did not exist until Appellant's invention is "virtually irrefutable" proof of its nonobviousness. *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1099, 227 U.S.P.Q. (BNA) 337, 348-49 (Fed. Cir. 1985).

This case is analogous to *Panduit*, where the Federal Circuit discussed the relevance of attempts and failures by others to develop a superior cable tie, a mechanically simple invention:

> That many others, including Dennison, had tried for years and failed to create a superior cable tie is virtually irrefutable evidence that the superior tie of the patents in suit would not have been obvious to those skilled in the art when it was invented.

*Panduit*, 774 F.2d at 1099, 227 U.S.P.Q. at 348-49. Here, too, Appellant's claimed invention is mechanically simple, yet its satisfaction of a longfelt need to safely and conveniently console newborn patients provides "virtually irrefutable evidence" of its nonobviousness.

The Examiner improperly disregarded this longfelt but unmet need evidence on the ground that it failed to "present any unexpected evidence." 3/13/06 Office Action, p. 3. Again, the Office Action fatally confused longfelt but unmet need requirements with unexpected result requirements. The Office Action's demanded "unexpected evidence" is irrelevant to

consideration of whether the claimed invention satisfies a longfelt but unmet need. Indeed, the objective proof that the present invention satisfied a longfelt but unmet need soundly refutes the Office Action's unsupported, hindsight allegation that such a result was "expected."

An earlier Office Action similarly disregarded the longfelt but unmet need evidence because the "convenience and safety" of individual sucrose solutions "is the same advantage that any aseptic medicinal or food provides the user." 1/5/05 Office Action, p. 4. In so arguing, the Office Action knocked down the objective evidence by comparing it to a prior art part of the recited invention, as opposed to the recited invention as a whole. The Office Action is basically saying that because the distinguishing elements of the claimed combination are known individually in a different context, there can be no evidence of longfelt but unmet need. This reasoning defies the logic of longfelt but unmet need rebuttal evidence. Under such an analysis, all objective evidence could be ignored based on the assertion that a given feature and its benefits are known in the art, because presumably every *prima facie* case of obviousness teaches all the elements of the claim, but not in the same combination as claimed. As such, an Examiner could always point to some feature as already being known (assuming a proper *prima facie* case with all the claim elements in the prior art has been made) and take the same conclusory position as the Office Action in this application. However, the point of longfelt but unmet need evidence is to show the satisfaction of a longfelt but unmet need for the entire claimed invention. It is impermissible for the Office Action to disregard this evidence on the basis of individual elements or their benefits being known, particularly where those individual elements did not satisfy the longfelt need, as explained and proven above.

Thus, Appellant has provided compelling objective evidence of a longfelt but unmet need for the presently claimed invention. The Office Action should have substantively found the present claims nonobvious for this reason. Moreover, the Office Action procedurally disregarded this evidence for improper reasons. For at least these reasons, the pending obviousness rejection should be reversed on both substantive and procedural grounds.

**d. The Office Action's failure to weigh the objective evidence as a whole against the alleged prima facie case necessitates reversal**

A review of the Examiner's treatment of the Appellant's rebuttal evidence in general shows that, in essence, to the extent the Examiner substantively considered the evidence at all, the Examiner considered each individual piece of rebuttal evidence for its ability to "knock

down" the alleged *prima facie* case of obviousness, which is legally impermissible. *In re Piasecki*, 745 F.2d 1468, 1472-73, 223 USPQ 785, 788 (Fed. Cir. 1984). Instead, when rebuttal evidence is presented, any *prima facie* case of obviousness is dissipated, and all the evidence must be reconsidered in reaching the final conclusion on the issue of obviousness. *Id.*, 745 F.2d at 1472-73, 223 USPQ at 788. That is, the presentation of rebuttal evidence eliminates the procedural presumption afforded to the alleged *prima facie* case, and all the evidence must be reconsidered anew in its entirety. *Id.*, 745 F.2d at 1472-73, 223 USPQ at 788.

Here, however, it is clear from the record that the Office Action did exactly what the Federal Circuit prohibits, and analyzed each individual category of rebuttal evidence submitted by Appellant for its ability to "knock down" or overcome the alleged *prima facie* case of obviousness. Nothing in the record indicates that the Examiner ever considered the totality of the rebuttal evidence as a whole. And nothing in the record indicates that the Examiner ever set the alleged *prima facie* case aside and reconsidered all the evidence anew. Instead, for each category of such rebuttal evidence, the record is clear that the Examiner simply analyzed it alone and discounted it as being insufficient to rebut what the Examiner considered to be the *prima facie* case, allowing the Examiner's *prima facie* case to remain impermissibly "set in concrete." *Id.*, 745 F.2d at 1472, 223 USPQ at 788. There was not a single indication in the record that the Examiner took the proper approach and considered all the evidence (both for and against obviousness) anew in its entirety, as is legally required. Thus, the approach taken by the Examiner with respect to the objective evidence is exactly the approach prohibited by *In re Piasecki*.

At the very least, Appellant is entitled to have the rebuttal evidence presented considered in its entirety and in a procedurally proper manner. Here Appellant not only submits that the Office Action reached the wrong substantive conclusion on obviousness, but that the Office Action also did so in a procedurally improper way.

Because the analysis applied by the Examiner to the objective evidence was legally flawed, the result cannot stand and requires reversal for this additional reason.

### 3. The Board should reverse the pending rejection of claims 1-4, 6, 7, 10, 21, and 23-36

There is no *prima facie* case of obviousness because there was no obvious suggestion, motivation, or other reason to have made the Office Action's proposed combination of prior art.

Even if a *prima facie* case of obviousness were presented, Appellant's objective evidence of adulation for the invention, commercial success of the invention, and longfelt but unmet need for the invention each individually demonstrate the nonobviousness of the presently claimed invention. When combined, this objective evidence substantively compels a finding of nonobviousness. Moreover, the Office Action's failure to consider all of the objective evidence and alleged *prima facie* case anew in its entirety was improper.

Further still, as explained above, the Office Action individually disregarded Appellant's objective evidence of commercial success and longfelt but unmet need using legally erroneous standards. Such erroneous disregard for Appellant's evidence requires reversal of the pending obviousness rejection for this procedural defect as well.

Accordingly, Applicant respectfully requests the reversal of the pending obviousness rejection of independent claims 1, 23, and 29, as well as their respective dependent claims, which are patentable at least because they depend from patentable independent claims.

**B. The rejection of claims 12, 13, 15-17, 19, 20, 22, and 37-39 under 35 U.S.C. § 103 as obvious over AAPA, the Stevens 1997 article, the Stevens 1999 article, the Franck article, the Seattle Post-Intelligencer article, the Wisconsin State J. article, in view of Lazure further in view of Beckers and Hendriks, Bublitz, further in view of Koch, Corbic, Lane, Sharkey, Stockdale, Meisner, and Christine, and further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article.**

Appellants also appeal the rejection of claims 12, 13, 15-17, 19, 20, 22, and 37-39 under 35 U.S.C. § 103 as obvious over AAPA, the Stevens 1997 article, the Stevens 1999 article, the Franck article, the Seattle Post-Intelligencer article, the Wisconsin State J. article, in view of Lazure further in view of Beckers and Hendriks, Bublitz, further in view of Koch, Corbic, Lane, Sharkey, Stockdale, Meisner, and Christine, and further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article.

**1. Claims 12, 13, 15-17, 19, 20, and 22**

Independent claim 12 recites, among other things, "preparing a solution comprising sucrose and water; packaging the solution in single-use containers; [and] administering a selected volume dose of the solution orally to the neonatal infant." Independent claim 17 recites, among other things, "providing a solution comprising sucrose and water in an aseptic state and in a volume selected for single patient use within a sealed container; [and] administering the selected dose of the solution to the neonatal infant."

The rejection of independent claims 12 and 17 rests on essentially the same obviousness grounds as asserted against the other claims in this application and discussed above in Subsection VII.A. Appellant therefore traverses the obviousness of this combination for essentially the same reasons as discussed above in Subsection VII.A. Moreover, the objective evidence discussed above in Subsection VII.A.2 likewise compels a finding of nonobviousness of independent claims 12 and 17.

**a. Lazure Teaches Away From "Discarding Any Residual Solution" As Recited In Claims 12 and 17**

Appellant also traverses this rejection of claims 12 and 17 for an additional reason. Claim 12 recites, among other things, "discarding any residual solution within the opened, individual, single-use container after the planned medical procedure." Independent claim 17 similarly recites "discarding any residual solution with the container." In contrast, as explained above in Subsection A.1.a, Lazure's "unit dose" teaches away from including greater than a unit dose of medicine in a container and teaches away from administering less than the entire unit dose contents of the container. Here, the recited discarding of residual solution is entirely antithetical to Lazure's "unit dose" teaching, which critically focuses on administering the entire contents of the unit dose container. Thus, Lazure teaches away from the recited combination, and the recited combination is nonobvious for this additional reason.

Accordingly, Appellant respectfully requests the reversal of the pending obviousness rejection of independent claims 12 and 17 , as well as their respective dependent claims, which are patentable at least because they depend from patentable independent claims.

**2. Claims 37-39**

Independent claim 37 recites, among other things, "providing a cup-shaped container [] defining a cavity[]; transferring the sucrose solution into the cavity of the container; and sealing the container."

The rejection of independent claim 37 rests on essentially the same obviousness grounds as asserted against the other claims in this application and discussed above in Subsection VII.A. Appellant therefore traverses the obviousness of this combination for essentially the same reasons as discussed above in Subsection VII.A. Moreover, the objective evidence discussed above in Subsection VII.A.2 likewise compels a finding of nonobviousness of independent claim 37.

Accordingly, Appellant respectfully requests the reversal of the pending obviousness rejection of independent claim 37, as well as its dependent claims 38 and 39, which are patentable at least because they depend from patentable independent claims.

## VIII. CONCLUSION

In view of the foregoing, Appellant requests the reversal of the pending rejections of claims 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39.

Having overcome all objections and rejections, Appellant therefore respectfully requests allowance of the present application.

Please charge any fees associated with the submission of this paper to Deposit Account Number 14-1270. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Date: March 20, 2009

Philips Intellectual Property & Standards
1010 Murry Ridge Lane
Murrysville, PA 15668-8525

/Timothy Nathan/
Timothy Nathan
Reg. No.: 44,256
Tel. No.: (724) 387-4435
Fax No.: (724) 387-5021

Enclosures: Appendix IX. Claims Appendix
Appendix X. Evidence Appendix
Appendix XI. Related Proceedings Appendix

## IX. CLAIMS APPENDIX (37 C.F.R. § 41.37(c)(1)(viii))

The following pending claims 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39, as presented in Appellants' May 4, 2005 Amendment, are being appealed:

1. (Previously Presented) A packaged solution for use in conjunction with a planned medical procedure on a neonatal infant, comprising:

a cup-shaped container having a greater width than a depth and defining a cavity therein opening to a mouth;

a volume of a solution comprising sucrose and water within the cavity, wherein the solution comprises about 10% to about 50% sucrose with a remainder of the solution comprising water; and

a cover disposed over the mouth and sealing the solution within the cavity;

wherein the solution and an interior of the container are in an aseptic state.

2. (Previously Presented) The packaged solution of claim 1, wherein the cover includes a lateral protrusion extending beyond a lateral extent of the cup shape of the container.

3. (Previously Presented) The packaged solution of claim 2, wherein the container includes a peripheral flange about the mouth, and the cover extends peripherally at least to an outer end of the peripheral flange.

4. (Original) The packaged solution of claim 3, wherein the peripheral flange includes a lateral protrusion and the lateral protrusion of the cover is substantially aligned therewith.

6. (Previously Presented) The packaged solution of claim 21, wherein the container includes a peripheral flange about the mouth, and the cover extends peripherally at least to an outer end of the peripheral flange.

7. (Original) The packaged solution of claim 6, wherein the cover is sealed to the peripheral flange.

10. (Original) The packaged solution of claim 1, wherein the solution comprises about 24% USP grade liquid sucrose to about 76% clean water.

12. (Previously Presented) A method for providing a solution for use in conjunction with a planned medical procedure on a neonatal infant, comprising:

preparing a solution comprising sucrose and water;

packaging the solution in single-use containers;

assembling a plurality of the single-use containers in a shipping container;

shipping the shipping container to an intended site of usage of the solution;

opening an individual, single-use container of the solution prior to the planned medical procedure;

administering a selected volume dose of the solution orally to the neonatal infant; and

discarding any residual solution within the opened, individual, single-use container after the planned medical procedure.

13. (Previously Presented) The method according to claim 12, further comprising maintaining the solution in each single-use container in an aseptic state after packaging until opening thereof for the planned medical procedure.

15. (Previously Presented) The method according to claim 12, further comprising formulating the solution to comprise between about 10% and about 50% sucrose with a remainder of the solution comprising water.

16. (Previously Presented) The method according to claim 12, further comprising formulating the solution to comprise about 24% USP grade liquid sucrose to 76% clean water.

17. (Previously Presented) A method of administering a solution to a neonatal infant, comprising:

providing a solution comprising sucrose and water in an aseptic state and in a volume selected for single patient use within a sealed container;

opening the container;

withdrawing a selected dose of the solution from the opened container and administering the selected dose of the solution to the neonatal infant; and

discarding any residual solution with the container.

19. (Original) The method of claim 17, further comprising providing the solution as between about 10% and about 50% sucrose with a remainder of the solution comprising water.

20. (Original) The method of claim 17, further comprising providing the solution as about 24% USP grade liquid sucrose to about 76% clean water.

21. (Previously Presented) The packaged solution of claim 1, wherein the cover is sealed to the container.

22. (Previously Presented) The method according to claim 12, further comprising packaging solution in cup-shaped, single use containers having covers sealed over the mouths thereof.

23. (Previously Presented) A packaged solution assembly for use in conjunction with a medical procedure performed on an infant, the solution being orally administered to the infant by a user, the packaged solution assembly comprising:

a cup-shaped container having a width and a depth, the width being greater than the depth and defining a cavity therein opening to a mouth, the cavity further defining an inner surface, the cup-shaped container also includes a flange extending outwardly about the mouth, the flange includes a top surface, the container is constructed from a polymeric material;

a volume of a solution comprising sucrose and water disposed within the cavity, the solution comprising approximately 24% sucrose and approximately 76% water; and

a cover disposed over the mouth and sealing the solution within the cavity, the cover sealingly engaging at least a portion of the top surface of the flange, the cover further including a tab extending beyond the periphery of the flange such that the user can easily grasp and remove the cover.

24. (Previously Presented) The packaged solution assembly as recited in claim 23, wherein the cover is formed from a metal foil material.

25. (Previously Presented) The packaging solution assembly as recited in claim 23, wherein the cover is formed from a polymer film material.

26. (Previously Presented) The packaged solution assembly as recited in claim 23, wherein the cover is formed from a metallized insulating film.

27. (Previously Presented) The packaged solution assembly as recited in claim 23, wherein the peripheral flange includes a tab corresponding to the tab of cover.

28. (Previously Presented) The packaged solution assembly as recited in claim 23, wherein the solution and the interior of the container are in an aseptic state.

29. (Previously Presented) A packaged solution assembly for use in conjunction with a medical procedure performed on an infant, the solution being orally administered to the infant by a user via an object, the packaged solution assembly comprising:

a cup-shaped container having a width and a depth, the width being sized to receive at least a portion of an object, the cup-shaped container further includes a flange extending outwardly about the mouth, the flange provides a top surface;

a volume of a solution comprising sucrose and water disposed within the cavity, the solution comprises between approximately 10% and 50% sucrose in water; and

a cover disposed over the mouth and sealing the solution within the cavity, the cover sealingly engaging at least a portion of the top surface of the flange, the cover further including a tab extending beyond the periphery of the flange such that the user can easily grasp and remove the cover.

30. (Previously Presented) The packaged solution assembly as recited in claim 29, wherein the object is a pacifier.

31. (Previously Presented) The packaged solution assembly as recited in claim 29, wherein the object is a syringe.

32. (Previously Presented) The packaged solution assembly as recited in claim 29, wherein the cover is formed from a metal foil material.

33. (Previously Presented) The packaging solution assembly as recited in claim 29, wherein the cover is formed from a polymer film material.

34. (Previously Presented) The packaged solution assembly as recited in claim 29, wherein the cover is formed from a metallized insulating film.

35. (Previously Presented) The packaged solution assembly as recited in claim 29, wherein the peripheral flange includes a tab corresponding to the tab of cover.

36. (Previously Presented) The packaged solution assembly as recited in claim 29, wherein the solution comprises approximately 24% sucrose in water.

37. (Previously Presented) A method of producing a packaged solution assembly for use in conjunction with a medical procedure on an infant, the method comprising the steps of:

providing a cup-shaped container having a width and an depth, the width being sized to receive at least a portion of an object therein, the cup-shaped container defining a cavity

therein opening to a mouth, the cup-shaped container further comprising a flange extending about the mouth of the cavity;

mixing between approximately 10% to 50% sucrose with water to create a sucrose solution;

transferring the sucrose solution into the cavity of the container; and

sealing the container with a cover that is placed over the mouth and sealed with the flange of the container.

38. (Previously Presented) The method as recited in claim 37, wherein the object is a pacifier.

39. (Previously Presented) The method as recited in claim 37, wherein the object is a syringe.

## X. EVIDENCE APPENDIX (37 C.F.R. § 41.37(c)(1)(ix))

Appellants rely on the following evidence:

**A.** **Sweet-Ease Brochure**

**B.** **Declaration of Catherine N. Bush Under 37 C.F.R. § 1.132**

**C.** **Declarations of Don. T. Granger, M.D., Neal Guttenberg, M.D., and M. David Yohannan, M.D. Under 37 C.F.R. § 1.132**

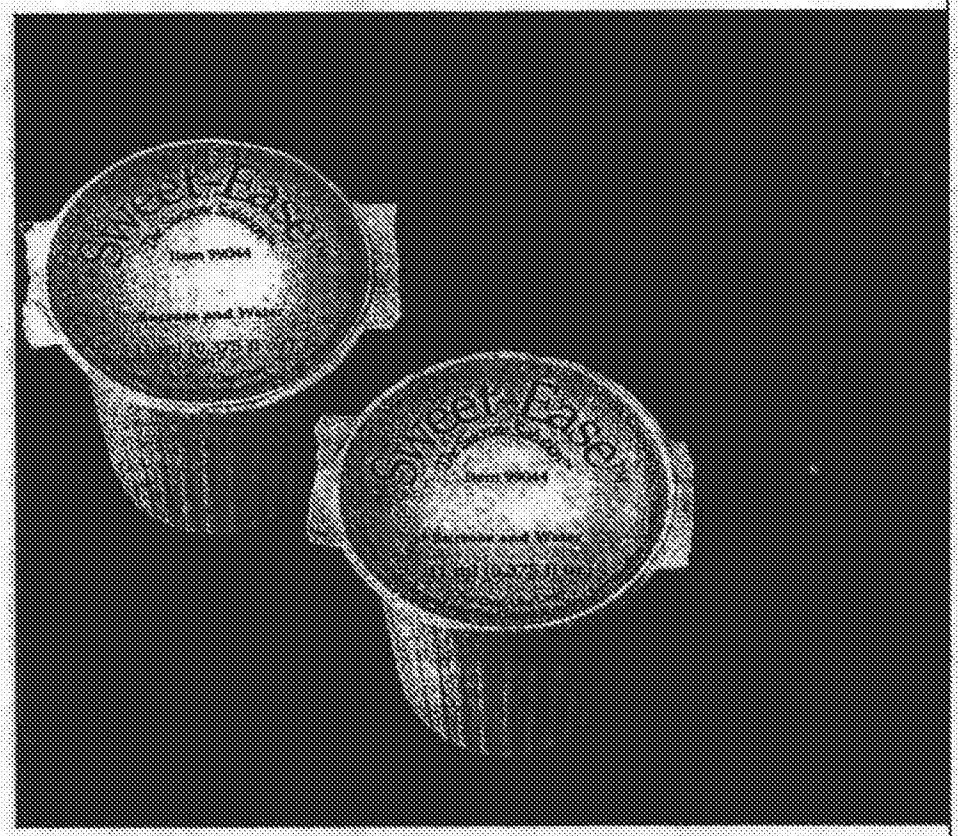
**D.** **TootSweet Brochure**

EXHIBIT A

Children's Medical Ventures

# Sweet-Ease™

The Sucrose Solution™



## Features

- Provides a safe and convenient method for oral sucrose delivery
- 24% concentration level*
- Packaged aseptically
- Preservative free
- 11ml cup with peel off lid is suitable for dipping a pacifier or administration via a dropper
- 6 month shelf life

## Benefits

- May be used in the NICU, PICU and Newborn Nursery
- Helps to calm and soothe babies in distress or during painful procedures *
- Aseptic packaging decreases risk of contamination
- Prepackaged solution prevents errors in preparation and saves time

1001 Murry Ridge Lane
Murrysville, PA 15668
www.childmed.com
www.respironics.com

* See bibliography on back.

MEDICAL DISPOSABLES

MEDICAL DISPOSABLES

# Sweet-Ease™

The Sucrose Solution™

## Specifications

- Ingredients: 24% sucrose, 76% water**
- 11ml of sucrose solution per cup
- Guaranteed aseptic in unopened, undamaged package
- Preservative free
- Packaged 200 cups per case (4 boxes of 50)
- Shelf life: six (6) months
- Latex free packaging

## Precautions

- For oral use only (not for injection)
- For hospital use only
- Do not reuse or sterilize
- Store at 40˚-90˚F (4˚-32˚C)
- Dispose of product after use

**Over a six (6) month period, concentration may increase to 40%

Patent Pending

## Instructions for Use

- Sweet-Ease™ should be used in compliance with standard hospital practices for oral sucrose delivery.
- See Instructions For Use in each 50 count box.

## Bibliography


Barr RG., Quek VSH., Cousineau D., Oberlander TF, Brian JA., Young SN. Effects of Intra-Oral Sucrose on Crying, Mouthing and Hand-Mouth Contact in Newborn and Six-Week Old Infants. Developmental Medicine and Child Neurology. 1994, 36, 608-618.

Blass EM., Smith BA. Differential Effects of Sucrose, Fructose, Glucose, and Lactose on Crying in 1- to 3-Day-Old Human Infants: Qualitative and Quantitative Considerations. Developmental Psychology. 1992, Vol. 28, No.5, 804-810.

Smith BA., Fillion TJ., Blass EM. Orally Mediated Sources of Calming in 1- to 3-Day-Old Human Infants. Developmental Psychology. 1990, Vol. 26, No.5, 731-737.

Taylor S. Aseptic Cartons. Food Product Design: Focus On New Technologies. 1999.


## Samples

Samples of Sweet-Ease™ are available. Please call Children's Medical Ventures at 800-345-6443 for further information.

## Ordering Information

| ITEM NO. | DESCRIPTION | QTY. |
|---|---|---|
| 99044 | Sweet-Ease™ The Sucrose Solution™ | 200/CS |

TO ORDER

CALL 1-800-345-6443

or 1-724-387-4000

www.childmed.com

www.respironics.com

1001 Murry Ridge Lane

Murrysville, PA 15668

EXHIBIT B

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION of

| | | |
|---|---|---|
| Inventor | : | DALY |
| Appln. No. | : | 09/670,781 |
| Conf. No.: | : | 6751 |
| Filed: | : | September 27, 2000 |
| Title: | : | SYSTEM, METHOD AND PACKAGE FOR PROVIDING A LIQUID SOLUTIION |
| Group Art Unit | : | 1761 |
| Examiner | : | Weinstein, S. |
| Docket No. | : | 00-39 |

* * * * *

August 27, 2004

**DECLARATION OF CATHRINE N. BUSH**

**UNDER 37 C.F.R. § 1.132**

Hon. Commissioner of Patents
and Trademarks
Alexandria, VA 22313-1504

Sir:

CATHERINE N. BUSH declares that:

1. I have been employed with Children's Medical Ventures, LLC (indirectly, a wholly owned subsidiary of Respironics, Inc.) ("CMV") since its inception in 1991. I am presently the Director of Strategic Marketing. When the SWEET-EASE ™ product was conceptualized and introduced to the market, I was the Vice President of Sales and Marketing. I was responsible for the product introduction, including marketing projections and sales/marketing tools.

2. I am familiar with the present U.S. Patent Application Serial No. 09/670,781 filed on September 27, 2000 entitled "System, Method and Package for Providing A Sucrose Solution."

3. The SWEET-EASE ™ product was introduced in the market in 2001. Since its introduction in 2001, the SWEET-EASE ™ product has experienced amazing success.

The market acceptance of the SWEET-EASE™ product has been surprising. In 2003, only 2 years after introduction, total sales were approximately 2.4 million cups for approximately $1.7 million in sales. This volume and adoption by the marketplace far exceeds both the typical growth of new products and our original expectations for this product.

4. For comparison purposes, CMV sells a heel warmer under the trademark HEEL HUGGER™. This product is used warm the sole of an infant's foot prior to a heel stick procedure. The HEEL HUGGER™ product has been in the marketplace for 5 years. In 2003, CMV sold approximately 400 thousand units. Therefore, in less than half the time, CMV has sold almost 6 times as many of the SWEET-EASE ™ product than of the HEEL HUGGER™ product.

5. I believe that these extraordinary sales results are because the SWEET-EASE™ product provides a convenient, aseptically packaged container filled with a sucrose solution not previously available in the medical industry. Research validating the effectiveness of sucrose to calm and soothe babies has been available since the late 1980's. However, because there was not a convenient, safe method for sucrose delivery, few hospitals were utilizing it even though it was shown to be effective.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

Respectfully Submitted,

Catherine N. Bush

Catherine N. Bush

CATHERINE N BUSH

Printed Name

8/20/04

Dated

EXHIBIT C

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION of

| | | |
|---|---|---|
| Inventor | : | DALY |
| Appln. No. | : | 09/670,781 |
| Conf. No.: | : | 6751 |
| Filed: | : | September 27, 2000 |
| Title: | : | SYSTEM, METHOD AND PACKAGE FOR PROVIDING A LIQUID SOLUTIION |
| Group Art Unit | : | 1761 |
| Examiner | : | Weinstein, S. |
| Docket No. | : | 00-39 |

* * * * *

August 26, 2004

**DECLARATION OF DON T. GRANGER, M.D.**

**UNDER 37 C.F.R. § 1.132**

Hon. Commissioner of Patents
and Trademarks
Alexandria, VA 22313-1504

Sir:

Don T. Granger, M.D. declares that:

1. I am a board-certified neonatologist and work in the Newborn Intensive Care Unit ("NICU") at the Children's Medical Center in Dayton, Ohio. The NICU at the Children's Medical Center is a 31-bed intensive care unit for high-risk newborns having medical or surgical problems.

2. The newborns admitted to the NICU are often very sick and require many painful or uncomfortable procedures. They may require blood to be drawn, venipunctures, IV starts, dressing changes, and catheter insertions. For some, these procedures may need to be performed multiple times every day.

3. I am familiar with the SWEET-EASE ™ product sold by Respironics, Inc. and have personally seen its commercial success in the marketplace.
4. I have personally seen sick newborns with elevated heart and breathing rates as a result of performing a procedure. I have also witnessed newborns that become unsettled and cry or vomit immediately following a procedure.

EXHIBIT C

5. Before the SWEET-EASE ™ product was available, I, or an attending nurse, would attempt to console the newborn by rocking or patting, if feasible. However, many sick newborns under our care are in incubators, have been intubated, or for other reasons cannot be moved or picked up. Calming these newborns becomes quite difficult.

6. It is known that oral administration of a sucrose solution can calm and sooth newborns. However, manually mixing a sucrose solution could prove dangerous and even life threatening to these sick newborns since it would be difficult to properly sterilize the mixture. For this reason, I am unwilling to personally mix a sucrose solution or to instruct others to do so.

7. There has long been a definite need in our industry for some way to calm and sooth these newborns. I have personally longed for some way to ease these newborn's suffering and discomfort. The SWEET-EASE ™ product meets this need.

8. I have personally witnessed the administration of the SWEET-EASE ™ product to newborns before receiving a procedure. These newborns are much less distressed. The results have exceeded my expectations. Although I expected some calming effect, the degree of effectiveness I witnessed was unexpected. In some cases, I have seen newborns quietly lay still during a procedure following the administration of the SWEET-EASE ™ product.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

Respectfully Submitted,

Don T Granger md

Don T. Granger, M.D.

8-26-04

Dated

EXHIBIT C

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION of

| | | |
|---|---|---|
| Inventor | : | DALY |
| Appln. No. | : | 09/670,781 |
| Conf. No.: | : | 6751 |
| Filed: | : | September 27, 2000 |
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| Group Art Unit | : | 1761 |
| Examiner | : | Weinstein, S. |
| Docket No. | : | 00-39 |

* * * * *

August 26, 2004

**DECLARATION OF NEAL GUTTENBERG, M.D.**

**UNDER 37 C.F.R. § 1.132**

Hon. Commissioner of Patents
and Trademarks
Alexandria, VA 22313-1504

Sir:

Neal Guttenberg, M.D. declares that:

1. I am a board-certified neonatologist and work in the Newborn Intensive Care Unit ("NICU") at the Children's Medical Center in Dayton, Ohio. The NICU at the Children's Medical Center is a 31-bed intensive care unit for high-risk newborns having medical or surgical problems.

2. The newborns admitted to the NICU are often very sick and require many painful or uncomfortable procedures. They may require blood to be drawn, venipunctures, IV starts, dressing changes, and catheter insertions. For some, these procedures may need to be performed multiple times every day.

3. I am familiar with the SWEET-EASE ™ product sold by Respironics, Inc. and have personally seen its commercial success in the marketplace.
4. I have personally seen sick newborns with elevated heart and breathing rates as a result of performing a procedure. I have also witnessed newborns that become unsettled and cry or vomit immediately following a procedure.

EXHIBIT C

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7. There has long been a definite need in our industry for some way to calm and sooth these newborns. I have personally longed for some way to ease these newborn's suffering and discomfort. The SWEET-EASE ™ product meets this need.

8. I have personally witnessed the administration of the SWEET-EASE ™ product to newborns before receiving a procedure. These newborns are much less distressed. The results have exceeded my expectations. Although I expected some calming effect, the degree of effectiveness I witnessed was unexpected. In some cases, I have seen newborns quietly lay still during a procedure following the administration of the SWEET-EASE ™ product.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

Respectfully Submitted,

Neal Guttenberg

Neal Guttenberg, M.D.

8/26/04

Dated

EXHIBIT C

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION of

| | | |
|---|---|---|
| Inventor | : | DALY |
| Appln. No. | : | 09/670,781 |
| Conf. No.: | : | 6751 |
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| Title: | : | SYSTEM, METHOD AND PACKAGE FOR PROVIDING A LIQUID SOLUTIION |
| Group Art Unit | : | 1761 |
| Examiner | : | Weinstein, S. |
| Docket No. | : | 00-39 |

* * * * *

August 26, 2004

**DECLARATION OF M. DAVID YOHANNAN, M.D.**

**UNDER 37 C.F.R. § 1.132**

Hon. Commissioner of Patents
and Trademarks
Alexandria, VA 22313-1504

Sir:

M. David Yohannan, M.D. declares that:

1. I am a board-certified neonatologist and work in the Newborn Intensive Care Unit ("NICU") at the Children's Medical Center in Dayton, Ohio. The NICU at the Children's Medical Center is a 31-bed intensive care unit for high-risk newborns having medical or surgical problems.

2. The newborns admitted to the NICU are often very sick and require many painful or uncomfortable procedures. They may require blood to be drawn, venipunctures, IV starts, dressing changes, and catheter insertions. For some, these procedures may need to be performed multiple times every day.

3. I am familiar with the SWEET-EASE ™ product sold by Respironics, Inc. and have personally seen its commercial success in the marketplace.
4. I have personally seen sick newborns with elevated heart and breathing rates as a result of performing a procedure. I have also witnessed newborns that become unsettled and cry or vomit immediately following a procedure.

EXHIBIT C

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9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

Respectfully Submitted,

M. David Rutherford, M.D.

8-27-2004

Dated

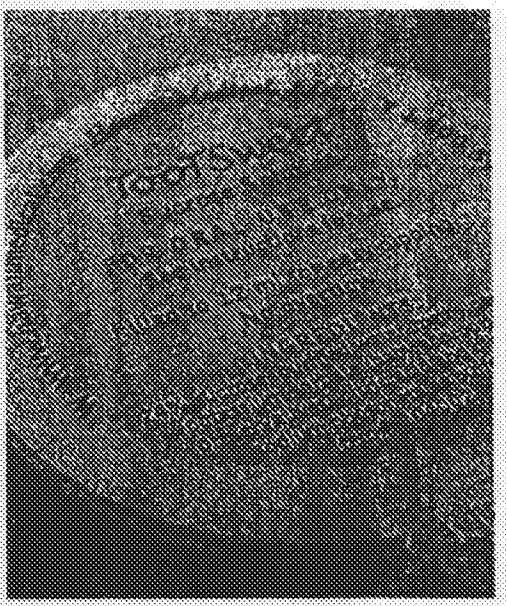
EXHIBIT D

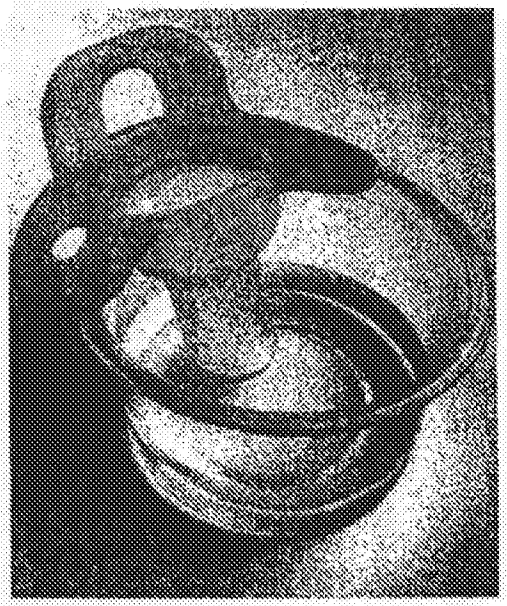
Hawaii Medical

# TootSweet™
## 24% Sucrose Solution

Economical and Convenient...TWO-Year Shelf Life!

- Economical and easy to use
- No refrigeration required
- Easy pacifier dipping – no tipping
- Stable container materials prevent changes in sucrose concentration
- Two-year shelf life





THE LARGE TOOTSWEET CUP ALLOWS EASY DIPPING OF OUR GUMDROP PACIFIER. PLENTY OF EXCESS SPACE ELIMINATES OVERFLOW.

Now there's a safe, convenient way to deliver sucrose solution to your babies – *TootSweet*™ 24% sucrose solution. TootSweet helps calm and soothe babies in distress and during painful procedures, while protecting against bacterial contamination.

- For preemie and full-term babies.
- Baby-appropriate preservatives prevent bacterial growth.
- Osmolarity buffered to range of mother's milk (260 mOsm/kg).
- 12 ml in a 30 ml cup. Single patient use.
- Large cup for easy pacifier dipping or transfer into an oral syringe for dose splitting (single patient use only) without spills.
- Stable container material keeps formulation consistent, eliminates evaporation, prevents increased sucrose concentration.
- Two-year shelf life reduces cost, inventory hassles, and waste.
- More economical and consistent than "homemade" solutions.

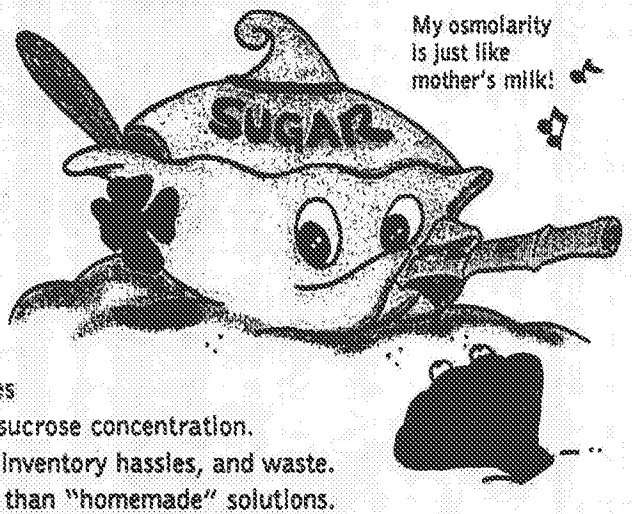


EXHIBIT D

## Keep Babies Safe and Save Your Hospital Money with Easy-to-Use TootSweet™!

Sucrose is a proven, effective method of helping to calm and soothe babies. It is also an ideal medium to grow bugs! Contamination can occur from airborne bacteria, contact with oral flora from re-dipped pacifiers or mucosal contact with oral syringes. Independent studies found non-preserved 24% sucrose became highly contaminated (53 large colonies, and small colonies too numerous to count) with bacteria and mold in a matter of hours after contact with a pacifier used by an infant. (Copy of report available on request.)

## TootSweet's Baby-Appropriate Preservatives Prevent Bacterial Growth and Extend Shelf Life.

TootSweet is preserved with methylparben and potassium sorbate, preservatives in Ora-Sweet™, Gentamicin, Caffeine Citrate, and other products commonly administered to preemies and full-term babies. So you can have confidence TootSweet is safe, whether you administer it by dose-splitting in oral syringes, or when using a pacifier. We tested our formulation in accordance with USP Preservative Effectiveness Test (27 NF 22 2004). ISO certified Toxikon Testing Laboratory separately inoculated 20ml aliquots of TootSweet with 1.0 x 106 of the following organisms: Aspergillus nigar, Candida albicans, Escherichia coli, Pseudomonas aeruginos and Staphylococcus aureus. The test results met current USP criteria for Antimicrobial Preservative Effectiveness Test.

## Instructions for Use

TootSweet has a two-year shelf life in un-opened containers. TootSweet is single patient use. TootSweet may be administered by ORAL only syringe (label appropriately), or by pacifier dipping. And remember, always follow your hospital protocols for sucrose use. Just a couple of drops on a pacifier or on the tip of the tongue, a few minutes before a procedure, is sufficient.

PRODUCT SPECIFICATIONS:
1 oz cup containing 12ml of 24% sucrose in purified water.
0.022% methylparben and 0.073% potassium sorbate as preservatives.
Citric acid and dibasic sodium phosphate as buffers to adjust osmolarity.

## Ordering Information

Give your babies the comfort and convenience of TootSweet! To place an order, request a sample, or find out more, please call Tri-anim, our national distributor at 1.800.874-2646.

## TootSweet 24% Sucrose Solution

| Part # | Description | Quantity |
|---|---|---|
| 1040021 | 1oz cups with 12ml 24% sucrose solution | Box of 40 |
| 1040022 | 1oz cups with 12ml 24% sucrose solution | Case of 240 (6 boxes) |

## Other Great NICU Solutions from Hawaii Medical

- *GumDrop Pacifier™*
  Incredibly soft! Silicone covers entire surface. Low profile design. No trimming to fit nasal tubes!
- *LifeGuard™ Electrodes*
  Electrodes that last, even in high humidity incubators.
- *LilyPad™ Pressure Relieving Mattress*
  Keeps babies more comfortable. Economical. Clean and re-use. Doesn't stain!
- *NeatNick™*
  Sweeping action heel lancet makes a neater nick. Is less painful for your babies. Costs less, too!
- *Save the Gonads™ X-Ray Shields*
  The first x-ray shields designed for babies, from micro-preemies to full-term newborns.
- *Shell-O™ Gel Pillow and Positioning Aid*
  Affordable, long-lasting gel support for babies of all sizes.
- *SunFish™ Locking Temp Probe Cover*
  Designed to lock the temp probe wire in place.

## Call for Product Samples or More Information

Hawaii Medical products are available for order from our national distributor, Tri-anim. For questions, product samples, or the sales representative in your area, please call 1.800.874.2646.

*Aloha from Boston!*

*Hawaii Medical*
Innovating Medical Products For Kids

*Hawaii Medical, LLC*
1730 Corporate Park | Pembroke, Massachusetts 02359
Tel 1.800.596.1555 Fax 781.826.2544
Web www.hawaiimedical.com

*NOT JUST A COMPANY... AN ATTITUDE!*

## XI. RELATED PROCEEDINGS APPENDIX (37 C.F.R. § 41.37(c)(1)(x))

There are no decisions rendered by a court or the Board in any proceeding identified pursuant to 37 C.F.R. § 41.37(c)(1)(ii).